I FENT COOPERATION TREA

	From the INTERNATIONAL BUREAU					
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NOTIFICATION OF ELECTION	Assistant Commissioner for Patents					
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(PCT Rule 61.2)	Office					
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	ETATS-UNIS D'AMERIQUE					
Date of mailing (day/month/year)						
04 October 2000 (04.10.00)	in its capacity as elected Office					
International application No.	Applicant's or agent's file reference					
PCT/FI00/00126	31762					
International filing date (day/month/year)	Priority date (day/month/year)					
18 February 2000 (18.02.00)	22 February 1999 (22.02.99)					
Applicant						
SUHONEN, Jouko						
SUNCINEIN, JUURU						
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1. The designated Office is hereby notified of its election made	e:					
X in the demand filed with the International Preliminary	Examining Authority on:					
28 August 2000 (28.08.00)						
in a notice effecting later election filed with the International Bureau on:						
2. The election X was						
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	Juan - July 20 and lies within the time limit under					
made before the expiration of 19 months from the priority Rule 32.2(b).	date or, where Rule 32 applies, within the time limit under					
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The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland

Authorized officer

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Telephone No.: (41-22) 338.83.38

Facsimile No.: (41-22) 740.14.35

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

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Applicant's or agent's file reference 31762	FOR FURTHER ACT		ration of Transmittal of International Examination Report (Form PCT/IPEA/416)			
International application No.	International filing date	(day/month/year)	Priority date (day/month/year)			
PCT/FI00/00126	18.02.2000		22.02.1999			
International Patent Classification (IPC) o A 61 C 5/04	r national classification an	nd IPC7				
Applicant						
Suhonen Jouko						
Authority and is transmitted to th 2. This REPORT consists of a total of the transmitted to the transmitted	Authority and is transmitted to the applicant according to Article 36.					
These uniones consist of a count	of sheets					
3. This report contains indications re	lating to the following ite	ms:				
I Basis of the report	I Basis of the report					
II Priority						
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		overty, inventive step	and industrial applicability			
IV Lack of unity of inve	ntion					
V Reasoned statement citations and explana	under Article 35(2) with reations supporting such state	egard to novelty, inve	entive step or industrial applicability;			
VI Certain documents c	ited					
VII Certain defects in the	e international application					
VIII Certain observations	on the international applic	cation				
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Date of submission of the demand		Date of completion	of this report			
28.08.2000		26.07.2001				
Name and mailing address of the IPEA/S	E	Authorized officer				
Patent- och registreringsverket Box 5055	Telex 17978					
S-102 42 STOCKHOLM Facsimile No. 08-667 72 88	PATOREG-S	Jack Hedlu	· ·			
		Telephone No. 08-	102 23 00			

Form PCT/IPEA/409 (cover sheet) (January 1998)



INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/FI00/00126

I.	Basi	Basis of the report	
ı.	With	With regard to the elements of the international application:*	
	\boxtimes	the international application as originally filed	
		the description:	
		pages	, as originally filed
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		the claims:	
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	Ш	the drawings:	
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		pages	, as originally filed
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3.	With r	the language of a translation furnished for the purposes of international search (under Rule 23.1(b)) the language of publication of the international application (under Rule 48.3(b)). the language of the translation furnished for the purposes of international preliminary examination or 55.3). With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the oreliminary examination was carried out on the basis of the sequence listing: contained in the international application in written form. filed together with the international application in computer readable form. furnished subsequently to this Authority in written form. furnished subsequently to this Authority in computer readable form. The statement that the subsequently furnished written sequence listing does not go beyond the discinternational application as filed has been furnished. The statement that the information recorded in computer readable form is identical to the written seen furnished.	n (under Rules 55.2 and/ ne international
4.		The amendments have resulted in the cancellation of: the description, pages the claims, Nos. the drawings, sheet/fig This report has been established as if (some of) the amendments had not been made, since they ha	nun hoon considered to an
5. *	Repla	beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2 (c)).** Replacement sheets which have been furnished to the receiving Office in response to an invitation under	_
	in thi: and 7	in this report as "originally filed" and are annexed to this report since they do not contain amendments and 70.17).	s (Rules 70.16
**	Any r	Any replacement sheet containing such amendments must be referred to under item I and annexed to thi	is report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/FI00/00126

V.	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
	citations and explanations supporting such statement

1.	Statement			
	Novelty (N)	Claims Claims	1-22	YES NO
	Inventive step (IS)	Claims Claims	1-22	YES NO
	Industrial applicability (IA)	Claims Claims	1-22	YES NO

2. Citations and explanations (Rule 70.7)

The claimed invention relates to a device for filling and reinforcing an internal tunnel preparation in a tooth from which tooth approximal caries has been removed by means of the tunnel preparation.

The following documents are cited in the search report:

- (D1) DE 4011568 A1
- (D2) EP 0572947 A2
- (D1) relates to a method of filling the root of a tooth with a plastic filler material contained in a capsule, which is connected to a flexible tube made of rubber or similar material. The filler material is forced through the tube by a piston, which is inserted in the capsule.
- (D2) relates to a transparent elastic body applied to dental light-curable fillings for maintaining uniform pressure on the filling.

However, none of the documents mention anything about an elongated, flexible and punchable device containing a restorative material intended for filling and reinforcing an internal tunnel in a tooth from which tooth approximal caries has been removed by means of the tunnel preparation.

Consequently, the cited documents only disclose the general state of the art, which is not considered to be of particular relevance. Therefore, the claimed invention differs from what is disclosed in the cited documents and is considered to fulfil the requirements of novelty, inventive step and industrial applicability.

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER AC		cation of Transmittal of International y Examination Report (Form PCT/IPEA/416)					
International application No.	International filing date	(day/month/year)	Priority date (day/month/year)					
PCT/FI00/00126 18.02.2000 22.02.1999								
	International Patent Classification (IPC) or national classification and IPC7							
A 61 C 5/04								
Applicant								
Suhonen Jouko								
Sunonen deale								
This international preliminary exa Authority and is transmitted to the	mination report has been e applicant according to A	prepared by this Inter Article 36.	rnational Preliminary Examining					
2. This REPORT consists of a total of	of 3 sheets	s, including this cover	r sheet.					
been amended and are the b	This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).							
These annexes consist of a total or	fsheets	S.						
3. This report contains indications re	lating to the following ite	ms:						
I Basis of the report			•					
II Priority								
III Non-establishment of	opinion with regard to no	ovelty, inventive step	and industrial applicability					
IV Lack of unity of inver	ntion	•						
V Reasoned statement u citations and explanat	nder Article 35(2) with reions supporting such state	egard to novelty, inve	ntive step or industrial applicability;					
VI Certain documents cit	ed ·							
VII Certain defects in the	international application							
VIII Certain observations	on the international applic	cation						
Date of submission of the demand		Date of completion	of this report					
28.08.2000		26.07.2001						
Name and mailing address of the IPEA/SE		Authorized officer						
Patent- och registreringsverket	Telex 17978							
Box 5055 S-102 42 STOCKHOLM	PATOREG-S	Jack Hedlu	nd/Els					
Facsimile No. 08-667 72 88	782 25 00							

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/FI00/00126

I.	Bas	sis of the report	
1.	With	regard to the elements of the international application:*	•
	\boxtimes	the international application as originally filed	
		the description:	, as originally filed
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		pages	, filed with the demand
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		the claims:	as originally filed
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		pages, as	amended (together with any statement) under article 19
		pages	, filed with the demand
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		the drawings:	, as originally filed
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		regard to the language, all the elements marked above were available atternational application was filed, unless otherwise indicated under this elements were available or furnished to this Authority in the following	or furnished to this Authority in the language in which s item.
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	Щ	the language of the translation furnished for the purposes of internat	ional preliminary examination (under Rules 55.2 and/
		or 55.3).	
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		contained in the international application in written form.	
		filed together with the international application in computer readable	e form.
		furnished subsequently to this Authority in written form.	
	\Box	furnished subsequently to this Authority in computer readable form.	
		The statement that the subsequently furnished written sequence listing international application as filed has been furnished. The statement that the information recorded in computer readable for been furnished.	
4.		The amendments have resulted in the cancellation of:	
		the description, pages	
		the claims, Nos.	
		the drawings, sheet/fig	the state of the s
5.		This report has been established as if (some of) the amendments had beyond the disclosure as filed, as indicated in the Supplemental Box	(Rule /0.2 (c)).**
	in thi:	acement sheets which have been furnished to the receiving Office in rails report as "originally filed" and are annexed to this report since the 70.17).	esponse to an invitation under Article 14 are referred to by do not contain amendments (Rules 70.16
**	Any r	replacement sheet containing such amendments must be referred to u	nder item I and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

Claims

Claims

International application No. PCT/FI00/00126

YES

v.	Reasoned statement under Arcitations and explanations sup	or industrial applicability;			
1.	Statement			* * * * *	
	Novelty (N)	Claims Claims	1-22		YES NO
	Inventive step (IS)	Claims Claims	1-22		YES NO

1-22

2. Citations and explanations (Rule 70.7)

Industrial applicability (IA)

The claimed invention relates to a device for filling and reinforcing an internal tunnel preparation in a tooth from which tooth approximal caries has been removed by means of the tunnel preparation.

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Consequently, the cited documents only disclose the general state of the art, which is not considered to be of particular relevance. Therefore, the claimed invention differs from what is disclosed in the cited documents and is considered to fulfil the requirements of novelty, inventive step and industrial applicability.

INTERNATIONAL SEARCH REPORT

International application No.

		PC1/F1 00	\UU126				
A. CLA	SSIFICATION OF SUBJECT MATTER						
IPC7: A61C 5/04							
According	According to International Patent Classification (IPC) or to both national classification and IPC B. FIELDS SEARCHED						
	documentation searched (classification system follow	and he should not be a single of the single					
		ed by classification symbols)					
IPC7:							
	ation searched other than minimum documentation t	o the extent that such documents are included	d in the fields searched				
	FI,NO classes as above	· ·					
Electronic	data base consulted during the international search (r	name of data base and, where practicable, sea	rch terms used)				
C. DOCU	EMENTS CONSIDERED TO BE RELEVAN	Т					
Category*	Citation of document, with indication, where	appropriate, of the relevant passages	Relevant to claim No				
A	DE 4011568 A1 (SPEISER, SUSANN	IF PETRA)	1-22				
	17 October 1991 (17.10.91)		1-22				
A	ED 0572047 42 (MANDED 11110 115						
^	EP 0572947 A2 (MANDER, HANS WE 8 December 1993 (08.12.93)	RNER, DR.),	1-22				
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	documents are listed in the continuation of Bo	x C. X See patent family annex.					
-	ategories of cited documents I defining the general state of the art which is not considered	T later document published after the inter date and not in conflict with the applica	mational filing date or priority				
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n PCT/ISA/	/210 (second sheet) (July 1992)						

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No. 02/12/99 | PCT/FI 00/00126

	atent document d in search repo		Publication date	Patent family member(s)	Publication date
DE	4011568	A1	17/10/91	NONE	
EP	0572947	A2	08/12/93	DE 4217932 A	02/12/93

Form PCT/ISA/210 (patent family amex) (July 1992)

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WORLD INTELLECTUAL PROPERTY ORGANIZATION International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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A61C 5/04	Al	(43) International Publication Date:	31 August 2000 (31.08.00)

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(22) International Filing Date: 18 February 2000 (18.02.00)

(71)(72) Applicant and Inventor: SUHONEN, Jouko [FI/US]; 663

Garth Court, Yorktown Heights, NY 10598 (US).

22 February 1999 (22.02.99)

(74) Agent: OY JALO ANT-WUORINEN AB; Iso Roobertinkatu 4-6 A, FIN-00120 Helsinki (FI).

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Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of

(54) Title: DEVICE FOR RESTORATIVE DENTISTRY

(57) Abstract

This invention refers to a device for filling and reinforcing an internal tunnel preparation (1) in a tooth (2) from proximal access by aiming to keep the approximal margin as short as possible in order to prevent overhangs. The device is characterized by a closed first elongate and flexible container means (3) having one end provided with a tip or string (4) to enable insertion of said first container means (3) into

an interdental space adjacent the portion of said tooth (2), from which approximal caries has been removed, said first container means (3) being filled or fillable with a flowable restorative material (6), which is intended to flow into and fill said tunnel preparation (1) as soon as a hole has been punched into said first container means (3) for instance by means of a needle (8) through said tunnel preparation (1).

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(30) Priority Data:

990372

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Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL AM AT AU AZ BA BB BE BF BG BJ BR CA CF CG CH CI CM CU CZ	Albania Armenia Austria Austria Australia Azerbaijan Bosnia and Herzegovina Barbados Belgium Burkina Faso Bulgaria Benin Brazil Belarus Canada Central African Republic Congo Switzerland Côte d'Ivoire Cameroon China Cuba Czech Republic	ES FI FR GA GB GE GH GR HU IE IS IT JP KE KG KP KZ	Spain Finland France Gabon United Kingdom Georgia Ghana Guinea Greece Hungary Ireland Israel Iceland Italy Japan Kenya Kyrgyzstan Democratic People's Republic of Korea Republic of Korea Kazakstan Saint Lucia	LS LT LU LV MC MD MG MK ML MN MR MW MX NE NL NO NZ PL PT RO RU	Lesotho Lithuania Luxembourg Latvia Monaco Republic of Moldova Madagascar The former Yugoslav Republic of Macedonia Mali Mongolia Mauritania Malawi Mexico Niger Netherlands Norway New Zealand Poland Portugal Romania Russian Federation	SI SK SN SZ TD TG TJ TM TR TT UA UG US VN YU ZW	Slovenia Slovakia Senegal Swaziland Chad Togo Tajikistan Turkmenistan Turkey Trinidad and Tobago Ukraine Uganda United States of America Uzbekistan Viet Nam Yugoslavia Zimbabwe
CN CU	China Cuba	KR KZ	Republic of Korea Republic of Korea Kazakstan	PL PT RO	Poland Portugal Romania		

Device for restorative dentistry

This invention concerns a device for filling and reinforcing an internal tunnel in a tooth from which tooth approximal caries has been removed by means of a tunnel preparation and for preventing overhangs.

When human teeth are damaged through demineralisation process caused by bacterial acid attacks this occurs practically always on very specific tooth sites which have been colonized by cariogenic micro-organisms. Interproximal and occlusal tooth surfaces are the main colonization sites of aciduric and acidogenic mutans streptococci which are the main causative bacteria of human dental caries.

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Matrix bands made of metal or cellulose acetate and interdental wedges made of limited adaptable wood or nonadaptable plastic have been traditionally used as aids to restore cavities prepared into caries affected teeth according to G.V. Black's principles. Today's modern primary cavity management considers these aids and principles as obsolete, since they are absolutely too invasive, destructive and even problem creating. The technology of tooth restoration has definitively changed from macro- to microconservative management of the decay. It is no more necessary to extend the cavities for prevention since cariostatic restorative materials, such as fluoride releasing glass ionomers, are available. Also extension for retention is not necessary since adhesive restorative materials, such as composite resins, glass ionomers and compomers, can be bonded to tooth hard substances, enamel and dentin.

With increasing concerns about microleakage and possibility of overfilling, as far macroconservative management of large cavities treated with conventional Class II composite resin restorations and inlays is concerned, there is a desire to cut down especially on gum related approxi-

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mal and marginal perimeter of restorations. The shorter the margin of the cavity preparation, the less the potential for marginal breakdown, leakage and overfilling. Handling of composite resin and glass ionomer materials in conventional box like or round bevel shaped approximal cavity preparations is not easy, since these materials tend to "over flow" to overhangs below the gum line which then serve as niches for facultative anaerobic gram-negative flora to colonize. Several recent studies have shown that the type of oral microflora, which causes chronic periodontal infections, often accompanied with uneven vertical bone loss at the affected tooth site, spreads out during episodes of dental bacteremia to heart and other organs clogging arterias. This triggers severe health conditions, such as coronary heart diseases, strokes and is also associated with pre-term low birthweight infants (Mattila et al. 1989, Syrjänen 1990, DeStefano et al. 1993, Beck et al. 1996, Joshipura et al. 1996, Herzberg & Meyer 1996, Scannapieco & Mylotte 1996, Grossman et al. 1997, Dasanayake 1997, Curtis 1997). When gums become inflamed due to contact with a marginal foreign body (overfilled restoration) and on it growing bacterial plaque, gingival sulcus is lined by an ulcerated epithelium. Capillaries beneath such an epithelium bleed spontaneously even after passage of food or a toothbrush over the gingival margin and allow different bacterial species to enter and survive in the bloodstream. Alone stroke incidence in the U.S. is dramatically higher than once thought. Some 700.000 occur each year, 40% more than previously estimated (Time magazine's citation from Journal of the American Medical Association and Stroke, 1998). It seems clear that overhangs/overfillings of dental restorations, which maintain chronic periodontal inflammation breaching the mucosal lining are by all means to be avoided, then even normally harmless streptococci as commensals of the normal oral flora behave as thrombogenic agent after having encountered platelets in bloodstream (Herzberg 1996).

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Further conserns in conventional approximal cavity management, in which the marginal ridge has been removed to get access to the carious lesion, is the fact that direct composite resin restorations do not warrant stable contact points. This is due to difficulty to manipulate sticky or flowable composite material to tight contacts to the adjacent teeth. Open approximal contacts lead to food impaction and retention. This forsters plaque accumulation and makes its removal difficult which within a short time causes inflammation of the dental papilla, i.e. the gum part between two adjacent teeth, and marginal gingiva. Consequent gingival pocket formation and bleeding due to food impaction contributes to dental bacteremia. Also proximal wear of composites generally questions the feasibility of their use in contact areas (Ziemiecki et al. 1992; Wendt et al. 1996).

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The primary role of the restorative dentistry should be to restore what has been lost by the very disease itself and to preserve as much as possible of the remaining hard tissue, of intact enamel and dentin. As the initial carious lesion occurs underneath the contact point, underneath the marginal ridge, there is no need to destroy the contact point and the ridge to get access to carious lesion. Tooth's marginal ridge should by all means be preserved to ensure a stable approximal contact.

The understanding complex relationships had led to more accurate dental care. The need for operative treatment of approximal carious lesions depends on whether or not caries process has reached the dentin. The sensitivity of dental radio-graphs, i.e. the ability to correctly diagnose, for detecting interproximal caries was earlier reported to be 59.4% (Douglass et al. 1986). Cavity detection in approximal tooth surfaces by means of digital images, e.g. by using storage phosphor system, opens new possibilities to determine that very condition / "moment" when an

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early caries lesion has penetrated into dentin and a primary restoration is indicated, more accurately (Wenzel et al. 1991, Nielsen et al 1996, Svanaes et al. 1996). It is of importance to choose a restoration procedure that allows a simple and complete access to the lesion without destroying the tooth's own natural and stable contact point which practically is never affected by initial caries. The filling procedure itself should be chosen so that no new problems, such as marginal breakdown, microleakage and/or overfilling are created, which would have health hazardous consequences.

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Since widely used conventional tooth restoring procedures are unnecessarily radical, extensive and complex, simpler procedures have been sought. Microconservative "internal tunnel" preparation as described by Jinks 1963 as well by both Hunt and Kent independently 1984, presents a very sophisticated method to treat the carious proximal lesion without loosing the important natural contact point between two adjacent teeth. From the occlusal approach a small round bur is passed down starting through central main fissure until the dentinal "approximal" lesion which can be easily identified in the inside of the tooth as a dark brown/black stripe and/or by probe which sticks. As the dentin caries has been removed, the overlying porous enamel, through which the initial lesion has passed into dentin, can easily be identified as demineralized enamel and punched-out.

To ensure complete caries removal without weakening the marginal ridge unnecessarily, tunnel preparations are performed using extra fine instruments, preferably under an operating microscope similar to endodontic treatments. The operating microscope allows better visualization of the working field, ensuring that the caries process inside of the tooth is more readily inspected with bright illumination and magnification. The principles of microsurgery

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in restorative dentistry are relatively new and allow the clinician to perform the treatment so that the strength of

the prepared tooth remains 92% and more of the sound value

(Hill & Halaseh 1988).

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No doubt the ability of filling materials (also called cements, i.e. syntetic analogues for enamel and dentin) to support the marginal ridge with an underneath preparation increases as the diameter of the tunnel itself decreases. Tunnel cavities have been filled by introducing kneadable, low viscous or flowable restoration materials from the occlusal approach using conventional hand instrumental application of injection. To fill such a cavity of a small diameter through one opening, especially if the air escape is not optimally provided, is difficult, if not impossible. Indeed by conventional "orthograde" filling access air will be clogged in the cavity since the other end of the tunnel is closed by a matrix band. Air cushion hinders and impedes the complete filling of the tunnel. To gain maximal reinforcing and maximal strength of the restored tooth, it is of importance to fill the tunnel completely and bubble-free with an adhering material.

Glass ionomer cements, composite resins and their mixtures, also called compomers, are for the moment the materials of choice to restore tunnel preparations. It has been shown that a proper filling of a tunnel cavity with glass ionomer, the undermined marginal ridge can be considered reinforced and fracture susceptibility of the area is eliminated (Hill & Halaseh 1988). To prevent recurrent caries of the operated area, glass ionomer or other fluoride leaching or anti - mutans streptococci - agent containing/releasing materials are preferably to be used. It has been reported that composite resin materials containing Ag+ (silver) fillers or Apacider-fillers (Ag, Zn) or other antibacterial fillers hinder the growth of mutans streptococci (Yamamoto et al. 1996, Syafiuddin et al.

6

1997) and so reduce recurrent caries of the primarily treated area.

Whichever filling materials and devices are used, it is of utmost importance to have a proper control of the procedure. Two important characteristics which cause failures in conventional tunnel restorations when filled from occlusal approach are:

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- 1) Incomplete filling. Since visual control and air escape are not provided. There is no way to ensure the tunnel is filled completely until the very end. Use of injection cannulas does not solve this problem, since they cannot be pushed through the entire tunnel system. Cannulas are also too thick, since they have to have a certain diameter to be able to pass the viscous filling material.
 - 2) Overfilling. There is no visual control over concave tooth contours which may cause leakage under a conventional matrix band

The object of the present invention is to eliminate the above problems, which is achieved with a device according to the characterizing part of claim 1.

By means of this device an internal tunnel cavity can be filled and reinforced with a flowable restorative material e.g. an adhering synthetic filling material from approximal access, i.e. retrograde filling, while air escape from the tunnel cavity through an uncovered occlusal opening of said tunnel is guaranteed. A first flexible container means acts as a special interdental device and releases flowable restorative or filling material into the tunnel cavity from the approximal access.

According to a prefered embodyment the device is further provided with a second flexible container device, attached

7

or attachable to the first flexible container device by means of a string, which second container device is aimed to be used for sealing the approximal cavity perimeter, which may be very short, during a curing phase of the restorative material, as soon as the filling of the entire tunnel cavity has been completed.

Below the device according to the present invention will be described in more detail, with reference to the drawings, wherein

- Fig. 1 shows a schematic side view of a preferred embodiment of the device;
- 15 Fig. 2 shows a first and a second stage in inserting a device shown in Fig. 1 into an interdental space;
 - Fig. 3 shows a cross section A-A in Fig. 2;

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- Fig. 4 shows a top view of a stage where a first container means of the device has been pulled into the interdental space;
- Fig. 5 shows a cross section B-B in Fig. 4 at a stage when the tunnel preparation has been completely filled with a flowable restorative material;
- Fig. 6 shows a top view of a stage of light curing the restorative material with a second container means of the device pulled into the interdental space;
 - Fig. 7 shows a cross section C-C in Fig. 6 during the light curing;
- Fig. 8 shows a side view of a second embodiment of a device according to the invention;

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Fig. 9 shows a side view of a third embodiment of a device according to the invention;

- Fig. 10 shows a first stage of two alternative ways to insert a device shown in Fig. 9 into an interdental space;
 - Fig. 11 shows a cross section D-D in Fig. 10 according to one of the alternatives,
- 10 Fig.12 shows a top view of a stage where the first container means of the device shown in Fig. 9 has been pulled into the interdental space according to the both alternatives;
- Fig. 13a and 13b show a cross section E-E according to the first and the second alternative, respectively when the tunnel preparation has been filled with the flowable restorative material;
- Fig. 14 shows a stage where the second container means has been pulled into the interdental space and light curing of the restorative material is carried out;
- Fig. 15 and 16 show two alternative embodiments of the second container means filled with a photoluminicencing medium,
- Fig. 17 shows a further embodiment of the second container means provided with a flexible, transversally illuminating fiber optic, and an alternative embodiment of such a fiber optic;
 - Fig. 18 a-c show still a further emodiment of the second container means,

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Fig. 19 shows an embodiment of the second container means provided with a combination of chemiluminicence and fiber optic.

Fig. 20 and 20a show a side view of a further emodiment of the device according to the invention, and

Fig 21 and 21a show a further prefered embodiment of the device according to the invention, i.e. a multi functional device.

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The device comprises a closed first elongate and flexible container means 3 having on end provided with a tip or sting 4 to enable insertion of said first container means 3 into an interdental space 5 adjacent a portion of a tooth 2 from which approximal caries has been removed. The first container means 3 is prefilled or fillable with a flowable restorative material 6, i.e. an adhering synthetic filling material, which may be self, dual, chemically or light curable. The restorative material is intended to flow into and fill a tunnel preparation 1 extending through the tooth 2 as an occlusal access preparation from the center fissure of the tooth 2 to said interdental space 5. A hole 7 is intended to be punched into said first container means 3 for instance by means of a needle 8 brought into contact with the first container means through said tunnel preparation 1. A hemostat 15 can used to squeeze and wrap the first container means 3 in order to force the restorative material 6 into the tunnel preparation 1.

According to a prefered embodiment the first container means 3 is prefilled to about 60 to 80 % of its volume with the flowable restorative material. This enables the first container means 3 to be easily pulled into the interdental space 5 whereby the container means 3 simultaneously will be constricted by the contacting teeth.

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In order to effectively prevent overhangs a second closed and flexible container means 9 is attached or attachable to the device. According to a first prefered embodiment the second container means 9 is attached or attachable to the tip or string 4 of the first container means 3. If the string 4 of the first container means is stationary connected to the second container means 9 as shown in Fig. 1 a first step in inserting the device into the interdental space will comprise pushing the string 4 like a dental floss through the contact point 14 between the teeth 2 defining the interdental space 5, as shown in Fig. 2 and 3 of the drawing. The dotted line illustrate the position of string 4 at the end of said first step.

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- The second container means 9 may also be a separate unit provided with a ring or a string 10 at one end, which ring or string 10 is intended to be attached to the string 4 of the first container means 3 e.g. by means of a knot or the like, when said string 4 has been pushed through the contact point 14 into the interdental space 5 or threaded through the interdental space 5 adjacent a tooth 2 to be treated, and the first container means 3 has been pulled into said interdental space 5.
- The second container means 9 is advantageously prefilled to a predetermined thickness and resiliency with a medium 11 such as a liquid, a gas or a gel in order to seal a proximal tunnel opening when said second container means 9 has been drawn into said interdental space 5 on removing the first container means 3 from said interdental space 5, after said tunnel preparation 1 has been filled.

The medium 11 in the second container means 9 may be a photoluminiscencing medium enabling photocuring of the restorative material 6 filled into the tunnel preparation 1 by irradiation with visible light 12.

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According to another embodiment the second container means 9 is provided with an axially extending, flexible and laterally lighting fiber optic 11b enabling curing, by means of lasers, plasma arc or halogen light, of the dental restorative resin 6 filled into the tunnel preparation 1 from the first container means 3.

According to a further embodiment the second container means 9 includes a triboluminicence system, i.e a first medium 11, luciferin and a luciferas capcule 11a providing chemiluminescence when said container means 9 is squeezed or bent in order to break the luciferase capsule bringing both components into contact with each other.

The second container means 9 may also be provided with a combination of chemiluminescence 11,11a and a fiber optic 11b, whereby an initial soft polymerization can be carried out by means on chemiluminescence and the final polymerization is carried out means of fiber optic.

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If the flowable restorative material is a photocuring material, such as a light curable composite resin, it is prefered that the first flexible container means 3 is made of a photoblocking material, such as nylon, polyester, teflon or the like containing pigments which make the materials non-transparent for wave lengths which are used to polymerize such light curable materials. A suitable material is for instance a see through orange nylon or analogue material, which prevents photocuring as long as the restorative material is stored in the container means 3. The material of the second container means 9 should be transparent in order to enable light curing of the restorative material in the tunnel preparation 1 through said second container means.

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If the restorative material 6 is self, dual or chemically curable, both the first (3) and the second (9) container

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device may be manufactured of a transparent nylon or an analogue transparent material.

According to one embodiment the first flexible container means 3 is substantially cylindrical and the second container means 9 is cylindrical or slightly conical, widening against the end facing away from the first container means 3.

According to a preferred embodiment both container means 3 and 9 are provided with a triangular cross section as indicated in Fig. 20a and 21a, which shape more exactly corresponds to the shape of an interdental space 5. One longitudinal edge of the device can be provided with an outwardly extending fin 13, which is intended to be placed in the contact point 14 of the adjacent teeth 2, and will thus act as a guiding reference.

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A device with a triangular cross section may be manufactured of thin monofilms such as polyester, e.g. Mylar®, Pu Pont), nylon, teflon etc. films in thickness of 12 microns and more. Also multilayer films of polyester laminated with polyethylene and polypropylene having a thickness of 40-50 microns are suitable materials for both container means 3 and 9. These materials can be heat or laser welded to form container means having a desired geometric form, such as a prisma-like container means having a triangular cross section and planar end walls or a container means having a triangular cross section and a longitudinal outstanding fin 13 along one edge, the ends of said container means being squeeze welded to form end fins 61a, 16b parallel to the longitudinal fin 13. In the device the two container means 3 and 9 are connected to each other by means of a common end fin 16b.

According to a preferred embodiment the device comprises a number of sequential container means (I - VII), as shown

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in Fig. 21 and 21a, having a triangular cross section and connected to each other by means of common end fins 16b. The device is provided with a longitudinal outstanding fin 13 extending along the whole length of the device. The end fin 16a in the front end of the device is provided with a string 4 to facilitate the insertion of the device into an interdental space 5 and the device is then intended to be pulled step by step through the interdental space 5. The longitudinal fin 13 is provided with text indicating the purpose of each container means. In the shown embodiment the first container means I contains an etching gel intended for conditioning a tunnel prepartion 1 in a tooth 2 for 15 seconds, as indicated at the fin 13. The etching gel is intended to enter the tunnel preparation 1 through a hole 7 punched in said container means I for instance by means of a needle 8 as shown in Fig. 21b, brought into contact with said container means I through said tunnel preparation 1. Container means II contains air to be used for rinsing and drying the tunnel preparation 1. For that purpose a 3-ways syringe 17 as that shown in Fig. 21b can be used. By usind such a 3-ways syringe 17 two holes 7 and 7a have to be punched in said container means II, one hole 7 facing to the tunnel preparation and one hole 7a for inserting the needle 8 of said 3-ways syringe, through which rinsing liquid and drying air can be fed into said container means II and further into the tunnel preparation 1. Thus rinsing and drying and other treatments can be carried out from the interdental space 5 towards the occlusal surface of the tooth 2. Container means III is filled with a prime & bonding agent which then is fed into the tunnel preparation 2 through a hole 7 punched in the wall of said container means III in the same way as described above. The prime & bonding agent is allowed to react in the tunnel preparation for 20 seconds. Then container means IV containing air is pulled into the interdental space 5 and drying is carried out as described in connection with container means II for 5 seconds, after which

14

container means V, filled with air, is pulled into the interdental space 5 for closing the proximal opening during the light curing of the prime & bonding agent for 10 seconds. Container means VI containing a flowable restorative material is then pulled into the interdental space 5 and a hole 7 is punched as described above and the flowable restorative material 6 is pressed from the container means VI into the tunnel preparation 1 until it is completely filled, after which container means VII containing air is pulled into the interdental space 5 for preventing the restorative material 6 from flowing out from the tunnel preparation 1 into the interdental space, during final light curing of the restorative material, i.e. for preventing overhangs. For pressing each material from said container means I, III and VI and for closing the proximal opening of the tunnel preparation 5 by means of the container means V and VII a special pressing tool provided with rotatable rolls which can be pressed against that container means which has been pulled into the interdental space.

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According to an embodiment as shown in Fig. 8 and 9 the opposite end of the first flexible container means 3 is laser, heat or chemically bonded to the outlet opening 18 of a cartridge 19, filled with said flowable restorative material 6. Said cartridge 19 is adaptable to an applicator device 20, for instance a pistol like applicator device of Centrix Inc. The outlet opening 18 communicates with the cavity of said first container means 3, which in this embodiment is in a vacuumized, thin and flat condition before use.

According to a prefered embodiment of the invention the closed end of said first flexible container means 3 is attached, preferably by means of a string 4 or a seam to an end of a second closed and flexible container means 5.

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The device can be also be provided with a separate longitudinal closed and flexible second container means 9, one end of which is provided with a string 10, which is intended to be threaded through an interdental space 5 from one side before the string 4 of the first container means 3 is threaded into the same interdental space (5) from the opposite side. The cartridge 19 or the applicator device 20, is provided with a hook 21 or similar device, to which the string 10 of the second container means 9 can be hooked, so that the second container device is pulled into the interdental space 5 simultaneously as the first container means is removed from said interdental space 5, as will appear from Fig. 10, 11, 12, 13b and 14.

The string 10 of the second container means 9 can also be attached to the string 4 of the first container means 3 when the first container means 3 has been pulled into an interdental space 5, which also have been shown in Fig. 12, Fig. 13a and Fig 14.

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If the restorative material 6 in the cartridge 19 is of a light curable type the cartridge 19 should be photoblocked, preferably by using a see through orange plastics or a 100% photoblock material for manufacturing the cartridge 19.

The use of a device according to the invention is described below step by step.

- 30 A lesion and its relation to anatomic structures of a tooth 2 is located by means of a preoperative radiological digital image.
 - The affected tooth 2 is anesthetized.

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- After the placement of a rubber dum interdental accessories such as Wedjets dam cord as color indicator, fiber

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optic illumination and a metal matrix piece are used to guide and protect during the preparation procedure.

- An occlusal access preparation 1 is made into center fissure of the tooth 2 with a high speed, water-cooled bur or by means of air-abrasive technology, i.e. kinetic cavity preparation.
- In the fiber optic illumination bright yellow or red interdental cord (Wedjets) glimmer through the enamel guiding the operator to remove approximal caries but saving as much as possible of the intact enamel. Aim is to pass the bur underneath the contact point 14 between the damaged tooth 2 and an adjacent tooth through the enamel, just there where caries penetrated into the tooth 2. The interdental matrix band will protect the adjacent tooth.
- Caries removal is verified e.g. by caries detector, using hand-instrument probing, suitable rotary instruments and/or carisolv system in direct vision preferably under an operating microscope with bright illumination and magnification. However, microscope is only an option and is not necessarily needed.
- 25 Enamel margins of approximal and occlusal openings are finished by suitable diamond or tungsten carbide burs.
 - Wedjet dam cord and matrix band are removed.
- Smear layer is removed with air-water spray and then the tooth is gently dried by stream of warm air. If the multifunctional device shown in Fig. 21 is used it is pulled into the interdental space 5 before this stage, and the treatment is continued as previously described.

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- Tunnel-cavity is "primed" to receive filling material following the instructions of the manufacturer (primer / conditioner / etch gel / bonding resin -system).

- If for instance a device shown in Fig. 1 is to be used, 5 it is at this stage placed interdentally as previously described by pressing the string 4 as a dental floss through the contact point 14 from occlusal access and then pulling the first contained means 3 into the interdental space. The first container means is now squeezed by means 10 of a hemostat or the like in order to adapt said first container means 3 tightly on the approximal surfaces below the contact point 14 of the two adjacent teeth 2. The first container means 3 will now tightly cover the appro-15 ximal opening of the prepared tunnel cavity 1. If a device according to Fig. 8 or 9 is to be used the first container means 3 of it is pulled into the interdental space 5 in a flat and empty condition. The restorative material 6 in the cartridge 19 is then pressed by an applicator device 20 20 into the first flexible container means 3, which fills up and adapts itself tightly on the approximal surfaces below the contact point of the two adjacent teeth.
- The operator punches from the occlusal access through the prepared tunnel 1 a small hole 7 into the first flexible container means 3 with a suitable needle 8 (analogue to an endoinstrument). By maintaining a constant pressure inside the first flexible container means 3 by using the hemostat 15 or by pressing the applicator device 20, the flowable restorative material 6 will flow slowly from the first flexible container 3 into the tunnel 1 through the approximal access.
- The tunnel cavity 1 is then slowly filled by the resto-35 rative material 6 under bear eye control. As soon the material 6 has reached the margins of the occlusal cavity the pressure is released. The device is then pulled late-

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rally until the first flexible container means 3 is pulled out from the interdental space and the second flexible container means 9 takes its place, which preferably is prefilled to a predetermined thickness and resiliency with a resilient and medium 11. The second container means 9 is then squeezed by means of the hemostat 15, so that said container means 9 seals tightly the approximal opening of the filled tunnel cavity 1. While said second container means 5 is maintained pressurized the filling material is polymerized e.g. by using a three sited (partly trans enamel) light curing technique, utilizing any of the second container means 9 disclosed in Fig. 15 to 19. The curing time per site is 60 seconds or shorter. By using argon laser a curing time of 7.5 seconds or even less per site may be sufficient.

- The second flexible container device is then depressurized and removed by further pulling the whole device laterally away.

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- The occlusal surface of the tooth is then adjusted and polished. A fluoride solution, varnish, gel etc. is applied occlusally and interdentally. Due to the device according to the invention the approximal surface needs no checking for overhangs and marginal imperfections.

19

Claims:

5 1. A device for filling and reinforcing an internal tunnel in a tooth (2) from which tooth approximal caries has been removed by means of a tunnel preparation (1) and for preventing overhangs, characterized by a closed first elongate and flexible container means (3) having one end provi-10 ded with a tip or string (4) to enable insertion of said first container means (3) into an interdental space (5) adjacent the portion of said tooth (2), from which approximal caries has been removed, said first container means (3) being prefilled or fillable with a flowable restorative material (6), which is intended to flow into and fill 15 said tunnel preparation (1) as soon as a hole (7) has been punched into said first container means (3) for instance by means of a needle (8) brought into contact with said container means (3) through said tunnel preparation (1).

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2. A device according to claim 1, characterized in that said closed first container means (3) is prefilled to about 60 to 80 % of its volume with a flowable restorative material (6).

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- 3. A device according to claim 2, characterized in that a second closed and flexible container means (9) is attached or attachable to the device.
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- 4. A device according to claim 3, chraracterized in that the second container means (9) is attached or attachable to the tip or string (4) of the first flexible container means (3).
- 35 5. A device according to claim 4, characterized in that the second container means (9) is attachable to the string (4) of the first container means (3) by means of a ring or

a string (10) mounted to one end of said second container means (10), when said first container means (3) has been pulled into an interdental space (5) adjacent a tooth (2) from which approximal caries has been removed.

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- 6. A device according to claim 3, characterized in that the second container means (9) is prefilled to a predetermined thickness and resiliency with a medium (11) such as a liquid, a gas or a gel in order to seal a proximal tunnel opening when said second container means (9) has been drawn into said interdental space (5) on removing the first container means (3) from said interdental space (5) after said tunnel preparation (1) has been filled.
- 7. A device according to claim 6, characterized in that said medium (11) is a photoluminiscencing medium enabling photocuring of the dental restorative resin (6) filled into the tunnel preparation (1) by irradiation with visible light (12).

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- 8. A device according to claim 6, characterized in that the second container means (9) is provided with an axially extending, flexible and laterally lighting fiber optic (11b) enabling curing, by means of lasers, plasma arc or halogen light, of a dental restorative resin (6) filled into a tunnel preparation (1) from said first container means (3).
- 9. A device according to claim 6, characterized in that said second container means (9) includes a triboluminicence system, i.e. luciferin (11) and a luciferase capsule (11a) providing chemiluminescence when said container means (9) is squeezed or bent breaking said luciferase capsule (11b) and bringing both components into contact with each other.

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- 10. A device according to claim 6, characterized in that said second container (9) includes a combination of chemiluminescence (11,11a) and a fiber optic (11b).
- 11. A device according to claim 1, characterized in that the first flexible container means (3) is made of photoblocking nylon, preferably of a see through orange nylon or analogue material.
- 12. A device according to claim 3, characterized in that the first and the second flexible container means (3, 9) are made of transparent nylon or analogue transparent material.
- 13. A device according to claim 3, characterized in that the first flexible container means (3) is substantially cylindrical and the second flexible container means (9) is cylindrical or slighty conical, widening against the end facing away from the first container means (3).

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14. A device according to claim 3, characterized in that both flexible container means (3,9) are provided with a triangular cross section and having preferably one edge provided with a longitudinal outstanding fin (13).

15. A device according to claim 14, characterized in that the ends of the container means (3, 9) are squeeze welded to form end fins (16a,16b) parallel to the longitudinal fin (13) of said container means (3, 9), one end fin (16b) of each container means (3, 9) being common to both container means (3,9).

16. A device according to claim 15, characterized in that the device comprises a number of sequential container means (I - VII), connected to each other by common end fins (16b), the end fin (16a) in the front end of said device being provided with a string (4) to facilitate in-

22

sertion of said device into an interdental space (5), and the longitudinal fin (13) being provided with indications of the purpose of each container means (I-VII), which container means (I-VII) are intended to be pulled step by step into the interdental space (5).

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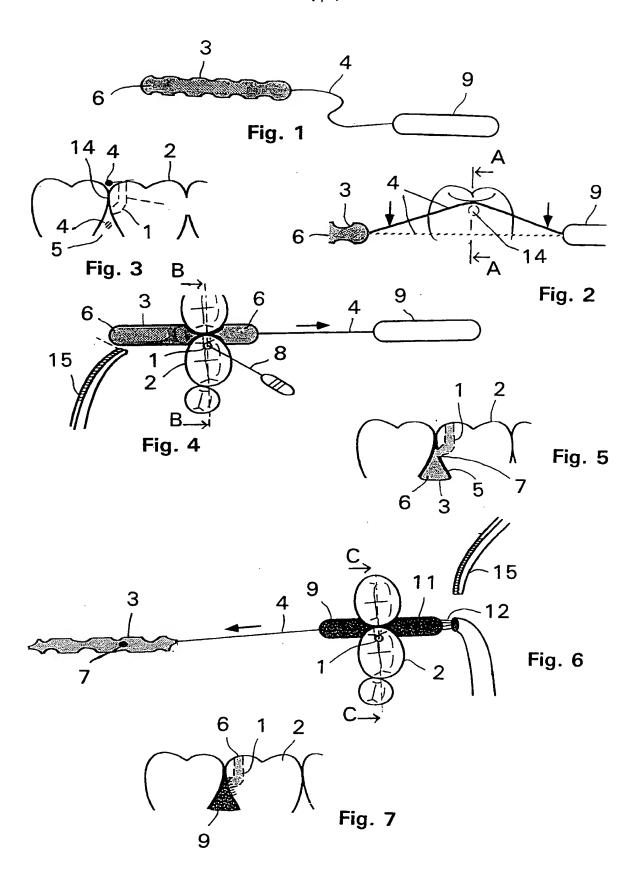
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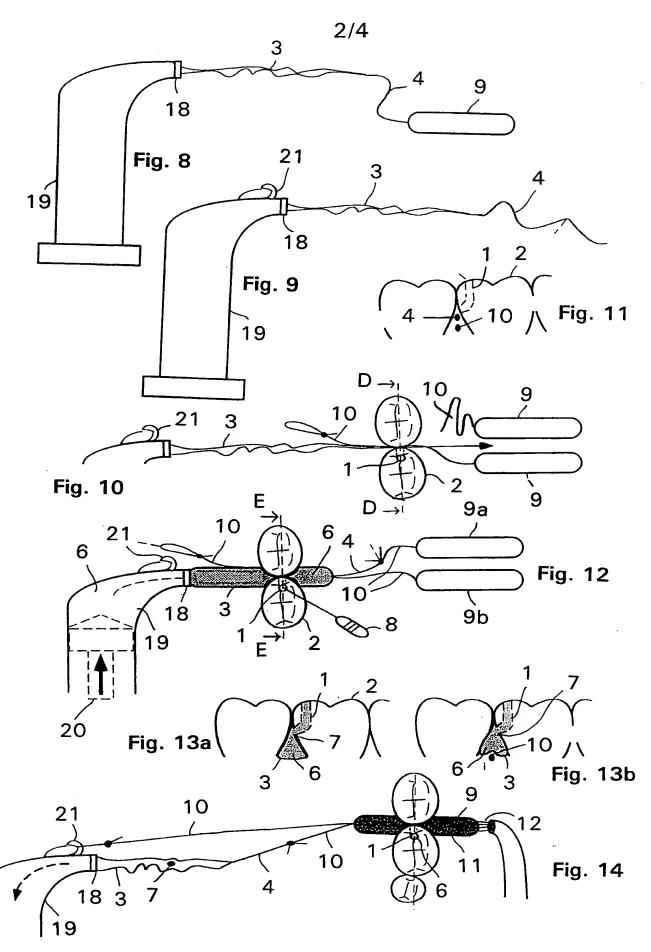
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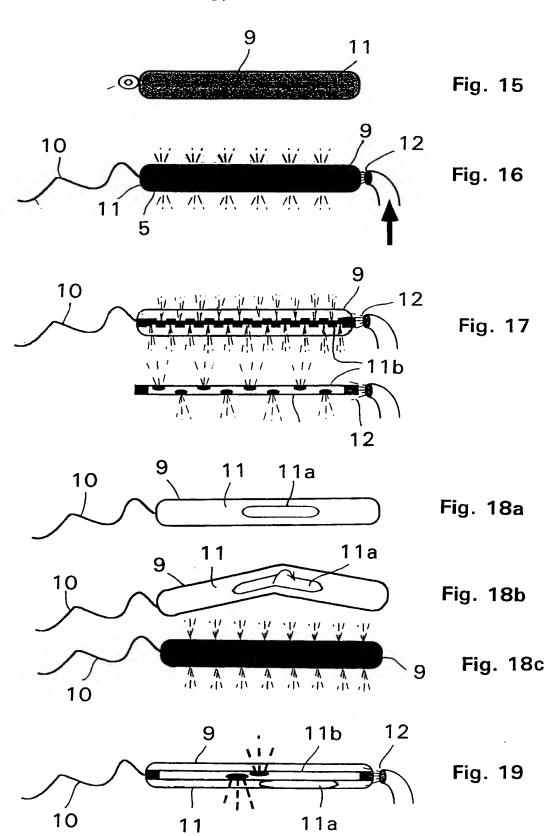
- 17. A device according to claim 1, characterized in that the the opposite end of the first flexible container means (3) is laser, heat or chemically bonded to the outlet opening (18) of a cartridge (19), filled with said flowable restorative material (6) and adaptable to an applicator device (20).
- 18. A device according to claim 17, characterized in that the first flexible container means (3) is in a vacuumized thin and flat condition before use.
- 19. A device according to claim 18, characterized in that a second closed and flexible container means (9) is attached or attachable to the device.
 - 20. A device according to claim 19, characterized in that the second container means (9) is provided with a string (10) at one end, which string is intended to be threaded through an interdental space (5) from one side before the string (4) of the first container means (3) is threaded into said interdental space (5) from the opposite side, whereby the cartridge (19) or the applicator device (20) is provided with a hook (21) to which the string (10) of the second container means (9) is intended to be hooked.
- 21. A device according to claim 19, characterized in that the second container means (9) is intended to be attached to the string (4) of the first container means (3) when said first container means (3) has been threaded into an interdental space (5).

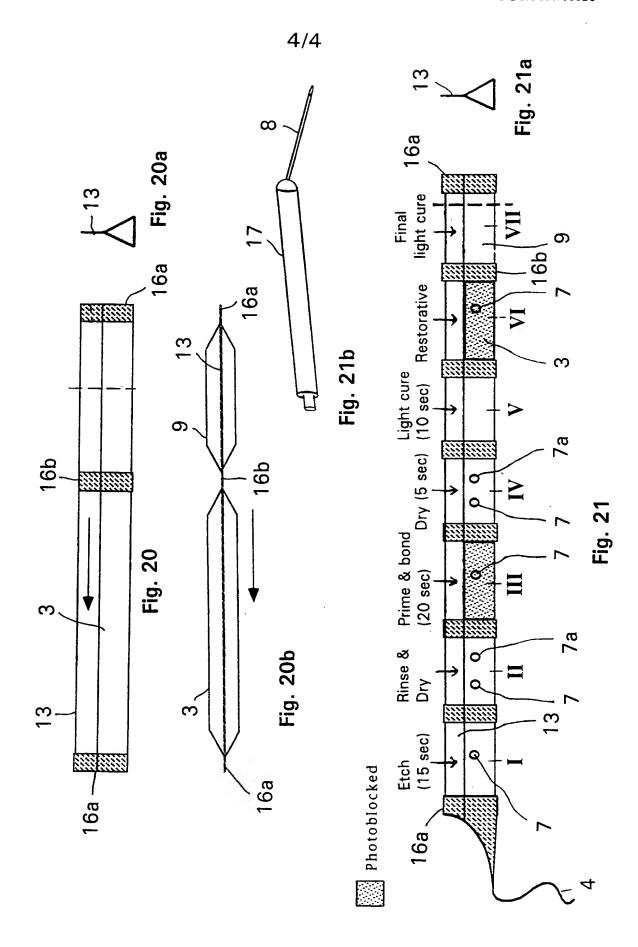
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22. A device according to claim 19, characterized in that the cartridge (19) is 100% photoblocked, or made by a see through orange photoblocked plastics.









INTERNATIONAL SEARCH REPORT

International application No.

PCT/FI 00/00126

A. CLASSIFICATION OF SUBJECT MATTER								
THE THE THE THE TENT OF SOBJECT MATTER								
IPC7: A61C 5/04								
According to International Patent Classification (IPC) or to both national classification and IPC								
B. FIELDS SEARCHED								
Minimum documentation searched (classification system followed by classification symbols)								
IPC7: A61C								
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched								
SE,DK,FI,NO classes as above		die neide betaeneg						
Electronic data base consulted during the international search (na	me of data base and, where practicable sear	ch terms used)						
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C. DOCUMENTS CONSIDERED TO BE RELEVANT								
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17 October 1991 (17.10.91)								
A EP 0572947 A2 (MANDER, HANS WER 8 December 1993 (08.12.93)	RNER, DR.),	1-22						
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Further documents are listed in the continuation of Bo.	x C. X See patent family annex							
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Information on patent family members

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Patent document cited in search report			Publication date	Patent family member(s)	Publication date
DE	4011568	A1	17/10/91	NONE	
EP	0572947	A2	08/12/93	DE 4217932 A	02/12/93

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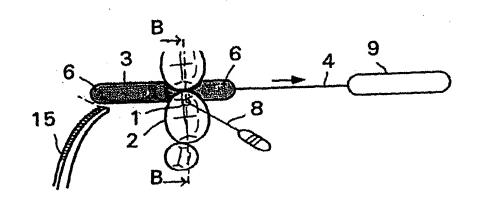
With international search report.

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(54) Title: DEVICE FOR RESTORATIVE DENTISTRY

(57) Abstract

This invention refers to a device for filling and reinforcing an internal tunnel preparation (1) in a tooth (2) from proximal access by aiming to keep the approximal margin as short as possible in order to prevent overhangs. The device is characterized by a closed first elongate flexible container means (3) having one end provided with a tip or string (4) to enable insertion of said first container means (3) into



an interdental space adjacent the portion of said tooth (2), from which approximal caries has been removed, said first container means (3) being filled or fillable with a flowable restorative material (6), which is intended to flow into and fill said tunnel preparation (1) as soon as a hole has been punched into said first container means (3) for instance by means of a needle (8) through said tunnel preparation (1).